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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/444,711	11/24/1999	TIMOTHY J. YEATMAN	114205.400	9003

21269 7590 01/02/2002

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EXAMINER

HARRIS, ALANA M

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 01/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/444,711

Applicant(s)

YEATMAN ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

1. Claims 29-38 are pending.

Claims 29-38 have been added. Claims 33 and 34 will be examined with this group to the extent that the transgenic cell is a recombinant cell.

Claims 1-28 have been cancelled.

Claims 29-38 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Drawings

3. The Applicants have acknowledged the Examiner's objection to the drawings and respectfully defer filing formal drawing until allowance of the claims is indicated

Withdrawn Rejections

Claim Rejections - 35 U.S.C. § 112

4. The rejection of claim 25 is rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement commensurate with the scope of the claimed invention is withdrawn in light of Applicants' cancellation of the claim.

5. The rejection of claims 1, 3, 4, 9-11, 19 and 21-27 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in

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such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in light of the cancellation of the claims.

6. The rejection of claims 1, 3, 4, 9, 11 and 21-27 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the cancellation of the claims.

Claim Rejections - 35 U.S.C. § 102

7. The rejection of claims 3, 4, 9-11, 19 and 24 under 35 U.S.C. 102(b) as being anticipated by Cartwright et al. (Cell 49:83-91, April 10, 1987/Referenced on IDS) is withdrawn in light of the cancellation of the claims.

8. The rejection of claims 1, 9-11, 19 and 21-27 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Number 5,336,615 (August 9, 1994) is withdrawn in light of Applicants' cancellation of the claims.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

9. Claims 29-32 and 35-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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a. Claims 29, 35 and 37 are vague and indefinite for reciting "codon 531". It is not clear whether or not Applicants are referring to nucleotide 531 or amino acid residue 531. It would seem that the three adjacent nucleotides encoding the stop codon is approximately between nucleotides 1590-1593. Applicants are requested to clarify the phrase and designate the codon which is to serve as the termination or stop codon. Accordingly, the metes and bounds are unclear.

Claim Rejections - 35 USC § 102

10. Claims 29-36 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent number 5,336,615 (August 9, 1994). U.S. Patent #5,336,615 and the accompanying database sheets disclose an isolated polynucleotide encoding a mutant c-Src protein, wherein the polynucleotide has a codon 531 which is a stop codon comprising SEQ ID NO: 1 (see columns 21-28 and accompanying database sheets). The isolated polynucleotide was located downstream of a promoter (regulatory element), wherein transcription of the gene or part was initiated at the promoter contained within an expression vector/recombinant construct (see column 7, lines 51-55, and column 9, lines 1-5, 22-25). This oligonucleotide set forth in SEQ ID NO:1 is a mutant c-Src gene that inherently is capable of recognizing and distinguishing a mutant c-Src gene having a codon 531 from a wild-type c-Src gene. Bovine calf aortic endothelial host cells were infected with a retroviral vector containing the disclosed polynucleotide/oligonucleotide of SEQ ID NO: 1 (see column 13, line 66-column 14, line 2). Also disclosed are methods for producing, expressing and recovering the encoded

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protein (see column 11, lines 1-60 and Figure 2, bridging paragraph of columns 6 and 7).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claims 29-38 are rejected under 35 U.S.C. 103(a) as being unpatentable by U.S. Patent number 5,336,615 (August 9, 1994). The teachings of the patent have been discussed above. The reference does not teach a diagnostic kit comprising the oligonucleotides of the patent and the said controls of claim 37.

Although the claims recite a kit, no positive recitation of the kit ingredients/elements distinguishes the claim over the references. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to form a kit. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings well known in the art to place the recited oligonucleotides in a kit because it is a well-known convention in the art to place the recited elements in a kit for the advantages of convenience and economy, as well as the recited elements would provide an efficient mode of diagnosis.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris whose telephone number is (703) 306-5880. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 306-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.


ANTHONY C. CAPUTA
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Alana M. Harris, Ph.D.
Patent Examiner, Group 1642
December 20, 2001